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## **EUROPEAN PATENT APPLICATION**

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## (54) Method for a ventilator system and a ventilator system

(57) A ventilator system, comprising an inspiratory line (16), an inspiratory pressure meter (22), arranged to sense pressure in the inspiratory line (16), an expiratory line (24), an expiratory pressure meter (30), arranged to sense pressure in the expiratory line (24), and a connector device (8, 12, 14) for connecting a patient to the ventilator system, is described. Since the connector device (8, 12, 14), includes a first gas line

(12), connected to the inspiratory line (16), and a second gas line (14), connected to the expiratory line (24), gas will only be able to flow in one direction through the lines (12, 14, 16, 24). Pressure in the lungs (4) during inspiration can accordingly be directly measured by the expiratory pressure meter (30) during inspiration and by the inspiratory pressure meter (22) during expiration.

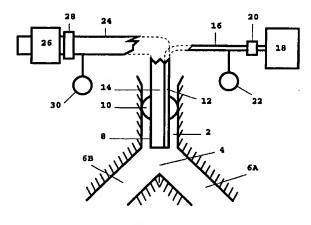


FIG. 1

The present invention relates to a method, for use with a ventilator system, for measuring pressure in a lung system during respirator treatment in which gas is 5 carried to the lung system during inspiration and carried

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away from the lung system during expiration.

The present invention also relates to a ventilator system comprising an inspiratory line, an expiratory line, an expiratory line, an expiratory pressure meter, arranged to sense pressure in the expiratory line, and a connector device, devised for placement at least in part in a patient's trachea, facing the carina, in order to connect the patient to the ventilator system.

One such ventilator system is described in WO-91/19526 and comprises a ventilator to which an inspiratory line and an expiratory line are connected. The inspiratory line and the expiratory line are attached, in turn, via a Y-piece to which a tracheal tube is also attached. The tracheal tube is intended for insertion into a patient's trachea in order to carry breathing gas to/from the patient's lungs. An inspiratory pressure meter is arranged in the ventilator unit to sense pressure in the ventilator system's inspiratory section and an expiratory pressure meter for sensing the pressure in the ventilator system's expiratory section.

Accurate sensing of pressure is important, the pressure in the patient's lung system in particular, i.e. pressure at the carina (the ridge separating the openings of the main bronchi at their junction with the trachea). Mainly as a result of the fall in pressure in the tracheal tube when breathing gas flows through it, the ventilator's pressure meters do not measure pressure in the lungs. Compensation for this fall in pressure must be made to obtain information on pressure at the carina, and determining this compensation can be difficult. The fall in pressure is dependent on e.g. flow in the tracheal tube. A number of methods can be used for calculating compensation for the fall in pressure.

US-A-4,265,237 describes a ventilator system in which a special pressure measurement tube is inserted into the tracheal tube to measure pressure in the lower part of same. If the pressure measurement tube is inserted all the way down to the carina, pressure can be measured there with good accuracy. However, blockage of the pressure measurement tube by secretions and other materials formed in the patient's lungs and lower airways is a problem which can occur in this type of measurement. So this procedure is very unreliable.

One object of the present invention is to solve the problems in known systems and achieve a ventilator system in which pressure measurements in the lungs can be performed simply and safely and with accurate results.

This object is achieved in accordance with the invention in that the method features the delivery of gas to the lung system via a separate first gas line and removal of gas from the lung system via a second separate gas line, whereby pressure in the lung system is

measured during inspiration by measurement of pressure in the second separate gas line.

This means that all gas flows to the patient's lungs through the first gas line during inspiration. Since no gas flows through the second line, no drop in pressure occurs across same. Pressure in the second gas line will then be the same as pressure at the carina. Measurement at some point in the second gas line will then also designate pressure at the carina.

SE-B-430 213 describes a ventilator system with two ventilator units. One of the ventilator units is set up as an ordinary ventilator, i.e. with inspiratory and expiratory lines connected to a common tracheal tube. The second ventilator unit has a separate supply line arranged inside the tracheal tube. In principle, breathing gas can be supplied, via the supply line, from the second ventilator unit, and gas can be carried away from the patient via the tracheal tube and expiratory line. However, this ventilator system is devised with a pressure measurement tube, like the one described above, to measure pressure in the carina.

One advantageous improvement of the method is achieved in accordance with the invention in that pressure in the lung system is measured during expiration by measuring pressure in the first separate gas line.

In the corresponding manner as in inspiration, all gas expired during expiration flows through the second gas line. No gas then flows in the first gas line, so there is no fall in pressure in this line either. Measurement of pressure in the first gas line also yields the pressure at the carina. Since new gas flows through the first gas line in every inspiration, this line is kept free from secretions and the like.

A ventilator system is achieved in accordance with the invention when the ventilator system according to the preamble is devised so the connector device comprises a first gas line, connected to the inspiratory line, and a second gas line, connected to the expiratory line, said gas lines being arranged so gas only flows through them in one direction, and pressure in the patient's lungs is measured during inspiration by means of an expiratory pressure meter.

Other advantageous embodiments of the invention are set forth in the dependent claims.

The invention will be described below in greater detail, referring to the figures in which

FIG. 1 shows a diagram of the most important components in a ventilator system, connected to a patient, according to the invention;

FIGS. 2A-2C show different designs for a tracheal tube in the ventilator system according to the invention;

FIG. 3 shows breathing curves and

FIG. 4 shows an alternative design for the ventilator system according to the invention.

FIG. 1 shows the lower part of a patient's trachea 2. It opens onto the carina 4 from which the main bronchi

across these lines is zero. The inspiratory pressure meter 22 then measures pressure at the carina 4.

6A, 6B lead down into the lungs. A tracheal tube 8 is in the trachea 2 and affixed with a cuff 10. The cuff 10 is inflatable and prevents gas from passing through the trachea around the tracheal tube 8. The tracheal tube 8 has a first gas line 12, through which breathing gas is supplied to the patient's lungs during inspiration, and a second gas line 14, through which breathing gas is carried away from the patient's lungs during expiration.

Here, the first gas line 12 is connected to an inspiratory line 16. The inspiratory line 16 is connected to an inspiratory valve 18 which regulates the supply of breathing gas to the inspiratory line 16. A flow meter 20 is arranged to measure the flow of breathing gas from the inspiratory valve 18, and an inspiratory pressure meter 22 is arranged to measure pressure in the inspiratory line 16.

In the corresponding manner, the second gas line 14 is connected to an expiratory line 24 which, in turn, is connected to an expiratory valve 26. The expiratory valve 26 regulates the flow of gas from the patient's lungs and/or pressure in the expiratory line 24 in the end phase of expiration. Here, a second flow meter 28 is arranged in the expiratory line 24 to measure the flow of breathing gas, and an expiratory pressure meter 30 is arranged to measure pressure in the expiratory line 24.

The inspiratory valve 18, the first flow meter 20, the inspiratory pressure meter 22, the expiratory valve 26, the second flow meter 28 and the expiratory pressure meter 30 can all be arranged in a ventilator unit (not shown). One such ventilator could be e.g. a Servo Ventilator 300, Siemens-Elema AB, Solna, Sweden. The ventilator unit can also consist of a ventilator unit according to the previously cited document, WO 91/19526 (Servo Ventilator 900 C, Siemens-Elema AB).

The unique features of the invention are that gas to/from the patient passes through completely separate gas lines 12, 14 and, particularly, that pressure at the carina is measured with the expiratory pressure meter 30 during inspiration and vice-versa. In this matter, pressure at the carina 4 can be measured with much greater accuracy than hitherto. Moreover, no calculation program is needed to determine compensation for the fall in pressure etc. in the tracheal tube. During inspiration, when breathing gas is supplied via the inspiratory line 16 and the first gas line 12, no gas flows in the second gas line 14 and the expiratory line 24. The expiratory pressure meter 30 then measures pressure at the carina 4, since there is no fall in pressure in the expiratory line 24 and the second gas line 14.

A small flow is permissible in the second gas line 14, as long as the fall in pressure which then develops there is negligible. Any fall in pressure can be measured with good accuracy when the flow is supplied in the first gas line 12, and pressure is measured in the second gas line 14.

In the corresponding manner, all gas flows through the second gas line 14 and the expiratory line 24 during expiration. No gas then flows through the first gas line 12 and the inspiratory line 16, so the fall in pressure The tracheal tube 8 with the first gas line 12 and the second gas line 14 can be devised in a plurality of ways, as shown in the tracheal tube cross-sections in FIGS. 2A, 2B and 2C. As in FIG. 1, FIG. 2A shows the first gas line 12 arranged inside the second gas line 14. The first gas line 12 can also be arranged parallel to and along-side the second gas line 14 (FIG. 2B) or integrated into the second gas line 14 (FIG. 2C). Additional embodiments of the tracheal tube 8, with two separate gas lines 12, 14, can be simply achieved.

The embodiment with separate gas lines 12, 14 also makes possible simpler pressure triggering in spontaneous breathing. Since the pressure meters 22, 30 measure pressure at the carina 4, any attempt at spontaneous breathing by the patient will be detected in the form of a fall in pressure at the carina 4. An inspiration can then be immediately supplied to the patient. In the corresponding manner, any attempt at expiration by the patient is quickly detected as an increase in pressure in the carina 4, and an expiration can then be triggered in a simpler manner than hitherto.

The trachea normally forms a dead space, i.e. gas which is rebreathed at the start of an inspiration. The entire tracheal tube forms a dead space to an intubated patient. Another advantage of the separate administration and removal of breathing gas is that the system minimizes the dead space.

The pressure meters 22, 30 can be simply checked against each other if pressure readings during inspiratory and expiratory pauses respectively, when no gas flows through any of the line 12, 14, 16, 24, are compared.

Triggering inspirations on the basis of flow measurements instead of pressure measurements, or a combination thereof, is desired in certain instances. A continuous basic flow of gas is then usually supplied via the inspiratory line 16. Flow is affected when the patient attempts to inhale, and an inspiration is triggered when flow has been affected to a sufficient degree. To minimize the impact of basic flow on pressure measurements in the present ventilator system, the system is devised in a specific manner described in greater detail in comments on FIG. 3.

FIG. 3 is a flow and time diagram showing a breathing curve 32. In FIG. 3, the breathing curve 32 covers two breathing cycles, a first inspiration 34A, a first expiration 34B, a second inspiration 34C and a second expiration 34D. Peak values for inspiratory flows and expiratory flows were set at 100%. They can be measured from breathing cycle to breathing cycle. The second flow meter measures flow during expiration. When flow drops to a pre-defined percentage of the peak value for flow, a weak basic flow of breathing gas is activated from the inspiratory valve. In this instance, 10% of the peak value for flow during the current expiratory 34B was used as the defined percentage. The patient will then be able to trigger an inspiration based on flow

measurement. When measured flow indicates a predefined inspiratory effort by the patient, as shown at point 38, the ventilator system is activated to supply an inspiration.

The basic flow supplied is small, and the fall in pressure in the second gas line 14 is therefore also small, so the pressure reading obtained by the expiratory pressure meter 30 can be used for relatively accurate determination of e.g. PEEP. A weighted value between the pressure measured by the inspiratory pressure meter 22 and the pressure measured by the expiratory pressure meter 30 can be used to attain greater accuracy.

The modest amount of breathing gas supplied during the latter part of expiration also conveys additional advantages. Gas evacuation of the lung is slight at the end of expiration and can be improved when the small additional gas flow supplied picks up some of the expired gas below the gas lines 12, 14. In this manner, the volume of dead space can be further reduced and  $\mathrm{CO}_2$  flushed out of the lungs. This flow can be eliminated in the breaths in which measurements are made of the concentration of expired  $\mathrm{CO}_2$ .

Limits other than 10% of the peak value for flow are also possible in determining when the basic flow is to be added.

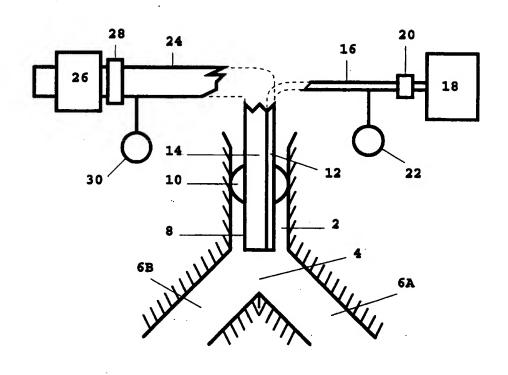
FIG. 4 shows an alternative embodiment of the ventilator system according to the invention. Components which can be identical have the same designations as in FIG. 1. So they do not need to described again. The major difference between the ventilator system according to FIG. 4 and the ventilator system according to FIG. 1 is that the ventilator in FIG. 4 has a separate tracheal tube 40, with only one gas channel, inserted into the patient's trachea 2 to carry away expired breathing gas in expiration. Gas supplied to the patient during inspiration is instead carried through a tracheotomy connector 42 to the patient's airway 2. In this instance, the tracheal tube 40 can be made relatively short and even avoid, in principle, passing the patient's vocal cords and damaging same.

## Ciaims

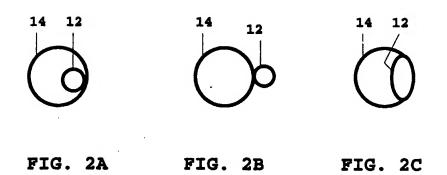
- 1. A method, for use with a ventilator system, for measuring pressure in a lung system during respirator treatment in which gas is carried to the lung system during inspiration and carried away from the lung system during expiration, characterized in that gas is carried to the lung system via a separate first gas line and carried away from the lung system via a second separate gas line, whereby pressure in the lung system is measured during inspiration by measurement of pressure in the second separate gas line.
- A method according to claim 1, characterized in that pressure in the lung system is measured during expiration by measurement of pressure in the first separate gas line.

- 3. A ventilator system comprising an inspiratory line (16), an expiratory line (24), an expiratory pressure meter (30), arranged to sense pressure in the expiratory line (24), and a connector device (8, 12, 14; 40, 42) devised for placement at least in part in a patient's trachea, facing the carina, in order to connect the patient to the ventilator system, characterized in that the connector device (8, 12, 14; 40, 42) comprises a first gas line (12; 42), connected to the inspiratory line (16), and a second gas line (14; 40), connected to the expiratory line (24), said gas lines (12, 14; 40, 42) being arranged so gas only flows through them in one direction, and pressure in the patient's lung is measured during inspiration by the expiration pressure meter (30).
- 4. A ventilator system according to claim 3, characterized in that an inspiratory pressure meter (22), arranged to measure pressure in the inspiratory line (16), is arranged to measure pressure in the inspiratory line (16), whereby pressure in the lungs is measured during expiration by the inspiratory pressure meter (22).
- A ventilator system according to claim 3 or 4, characterized in that the first gas line (12; 42) has a smaller cross-section than the second gas line (14; 40).
- 30 6. A ventilator system according to any of claims 3-5, characterized in that the connector device (8) is a tracheal tube.
- A ventilator system according to claim 6, characterized in that the first gas line (12) is arranged inside the second gas line (14).
- A ventilator system according to claim 6, characterized in that the first gas line (12) is arranged alongside and parallel to the second gas line (14).
  - A ventilator system according to any of claims 3-5, characterized in that the first gas line (42) consists of a tracheotomy connector, and the second gas line (40) consists of a tracheal tube.
  - 10. A ventilator system according to any of the above claims, characterized in that there is a valve system (18), connected to the inspiratory line (16) to supply a pre-defined flow of gas through the inspiratory line (16), a first flow meter (20), arranged to measure the flow of gas in the inspiratory line (16), and a second flow meter (28), arranged to measure the flow of gas in the expiratory line (24), said valve system (18) being devised to supply a pre-defined continuous flow of gas, during at least a latter part of an expiratory phase when the flow measured by the second flow meter (28) has dropped below a threshold value, said threshold value preferably

consisting of a pre-defined percentage of a peak value for flow measured by the second flow meter (28) during the expiratory phase.







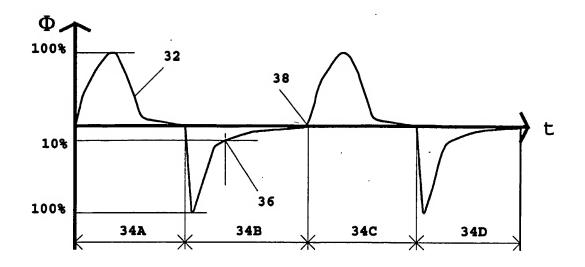


FIG. 3

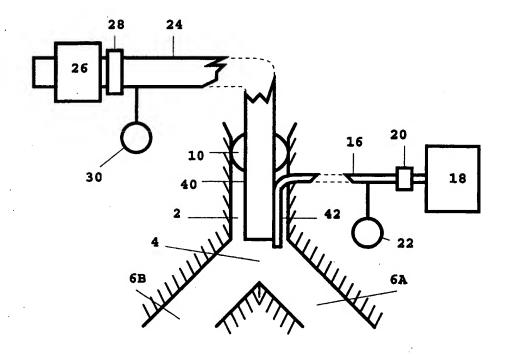


FIG. 4



## EUROPEAN SEARCH REPORT

Application Number EP 96 11 5981 Page 1

Category	Citation of document with of relevant	n indication, where appropriate, passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
4	WO, A1, 9401157 (P 20 January 1994 (2	MANG, HARALD), 20.01.94)	1-10	A61M 16/00 A61B 5/08
				TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61M A61B
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	The present search report has	been drawn up for all claims  Date of completion of the searce		Brancher
STOCKHOLM 18 February			i	Säfsten
X: par Y: par doo A: tec O: nor	CATEGORY OF CITED DOCUM ticularly relevant if taken alone ticularly relevant if combined with unment of the same category hnological background -written disclosure gradidate document	E : earlier pat after the fi another D : document L : document	rinciple underlying the	e invention illished on, or o

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